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**To:** Kathleen Jaeger; greg.herr@safeway.com; 'Susanne Hiland' (Susanne.Hiland@wal-mart.com); Don Bell; jhart@riteaid.com; eric.lessard@target.com  
**CC:** Davis, Thomas G.; Harrington, Nicole J.; Evan Schnur  
**Sent:** 6/14/2013 10:10:54 AM  
**Subject:** RE: Action Required: NACDS DEA Subcommittee: Draft Framework Document  
**Attachments:** NACDS Document Edits.docx

Please see a couple suggested edits.

Be well,

Tasha Polster, RPh  
Director, Pharmaceutical Integrity  
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Every day I help people **get, stay and live well.**

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**From:** Kathleen Jaeger [mailto:KJaeger@NACDS.org]  
**Sent:** Tuesday, June 04, 2013 4:12 PM  
**To:** Polster, Tasha; greg.herr@safeway.com; 'Susanne Hiland' (Susanne.Hiland@wal-mart.com); Don Bell; jhart@riteaid.com; eric.lessard@target.com  
**Cc:** Davis, Thomas G. (Thomas.Davis2@CVSCaremark.com); Harrington, Nicole J. (Nicole.Harrington@CVSCaremark.com); Evan Schnur  
**Subject:** Action Required: NACDS DEA Subcommittee: Draft Framework Document

Dear DEA Subcommittee Members,

A Draft Framework is attached for your review and consideration. We'd like to extend a special thanks to Tom and Nicole for putting the finishing touches on this Document! But many thanks to all of you since this document is the culmination of months of hard work on the part of this subgroup.

**Action Required:** We encourage you to review and comment on the draft by next Friday, June 14th.

It is our intention to send the draft document along (with submitted comments) to the full DEA Working Group for consideration.

Again many thanks for your leadership,  
Kathleen & Alex

PLAINTIFFS TRIAL  
EXHIBIT

**P-08439\_00001**

## **Framework to support pharmacist exercise of corresponding responsibility when evaluating controlled substance prescriptions**

### **Introduction**

In order for a prescription for a controlled substance to be valid, federal law (21 C.F.R § 1306.04(a)) requires that the prescription be issued for a legitimate medical purpose by a prescriber acting in the usual course of his or her practice. The rule places a ***corresponding responsibility*** upon the dispensing pharmacist to establish the validity of the prescription by ensuring the prescription is written for a legitimate medical purpose.

The purpose of this guidance document is to provide a structured framework to use when developing a continuing education program that may assist pharmacists when presented with prescriptions for controlled substances, to support the exercise of professional judgment while carrying out their corresponding responsibility under the law. This educational program will not be intended to replace pharmacist professional judgment in this regard, but rather to provide key reference points and information that the pharmacist can use to make professional, objective decisions.

The information presented in this guide is based upon actual behaviors, actions and trends observed by both health care prescribers in their practice and law enforcement and regulatory agencies in the course of their investigations of both prescriber and individuals involved in illegally prescribing, obtaining, or distributing prescription controlled substances. This program will not be considered as an all-inclusive list of considerations, but rather an initial framework to support decision making. To the extent that a pharmacist has concerns or information beyond those areas identified in this educational program, the pharmacist is still advised to include all relevant facts and information as part of their decision making process.

### **Framework for Decision Making**

When presented with a prescription for a controlled substance, there are three key lenses through which the prescription should be evaluated:

- 1 Prescriber Red Flags
- 2 Individual Red Flags
- 3 Prescription Red Flags

For each of these lenses, this guide will present the following information:

- **Red Flags** – These are areas of concern that the pharmacist could look for when evaluating the prescription. Red Flags represent behaviors, actions, or trends that have been observed or associated in cases where controlled substances have been prescribed or obtained illegally. Any Red Flags that are present should be resolved by the pharmacist as part of the decision making

process. In resolving Red Flags the pharmacist could consider available resources to obtain the information necessary when, in the exercise of their professional judgment, they believe this information will assist them in determining the appropriateness of filling a controlled substance prescription, to possibly include: referencing the state Prescription Drug Monitoring Program web site (in states where this is available), interviewing the prescriber, interviewing the individual, and consulting other pharmacists in the community (if indicated). Any Red Flag(s) that cannot be satisfactorily resolved by the pharmacist should be considered a significant cause of concern as part of the decision making process.

- **Key Considerations** – These are questions that the pharmacist could ask or consider when resolving a Red Flag.
- **Relevance** – This is information to provide additional context for each Key Consideration.

### I. Prescriber Red Flags

**1. Prescription is written by a prescriber located outside of the pharmacy's trade area**

**Key Considerations:**

- Why is the individual traveling to visit this prescriber?
- Is the prescriber engaged in a specialty practice that is not readily available locally?
- Is the prescriber part of a major medical institution or regional center of excellence where individuals would typically travel to seek specialized care (ex. Mayo Clinic)?
- Does the prescriber have an active DEA license?

**Relevance:**

- It is not uncommon for individuals to travel outside of their community to obtain legitimate medical care and services that are not readily available from local prescribers, or to receive care at nationally or regionally renowned medical institutions / centers of excellence – particularly in the case of rare or life-threatening diseases.
- Drug abusers are known to sometimes travel outside of their local area, and in many cases across multiple states, to obtain prescriptions for controlled substances from prescribers who are willing to write them for illegitimate purposes.
- Pharmacies can have the DEA license checked at the switch (with services like HDS and HMS)
- check the DEA license via the DEA website, call their local DEA office, or have it automatically checked by their computer software/vendors when processing a prescription.

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**2. Prescriber routinely prescribes large number (or percentage) of prescriptions for controlled substances relative to prescriptions for non-controlled substances**

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**Key Considerations:**

- Is the prescriber Board Certified in a specialty that typically utilizes the types and quantities of controlled substances being prescribed (examples: Pain Management, Oncology, Orthopedics, etc.)?
- Are the controlled substances being prescribed consistent with the diseases or conditions that would be treated by the prescriber's area of practice? Does the prescriber also write for non-controlled substances that are consistent with their area of practice? Is the prescriber's prescribing pattern similar to that of other prescribers (within same specialty) in the community?
- Are the ages of the individuals receiving controlled substances consistent with the prescriber's area of practice (i.e., is a pediatrician writing for a 50 year-old individual)?
- Are the controlled drugs prescribed in the identical or same chemical class? (i.e., opiates)

**Relevance:**

- Prescribing patterns exhibited by a prescriber should be taken into consideration by the pharmacist. In the usual course of legitimate medical practice, similar prescribing patterns are often observed among prescribers in a given specialty or area of practice. A common trend observed in established cases of abuse includes the disproportionate prescribing of controlled substances by the prescriber when compared to the prescribing habits of other prescribers in the same specialty or area of practice.
- There have been established cases of illegitimate prescribing of controlled substances where the prescriber's area of practice has not been consistent with either the drugs being prescribed or the ages of the individuals being treated (example: a pediatrician prescribing narcotic analgesics for adults).

**3 Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals**

**Key Considerations:**

- Are the controlled substance quantities and directions being prescribed consistent with the diseases or conditions for each individual? (e.g. long acting narcotics being prescribed for chronic pain verses short-acting narcotics for chronic pain)
- Are most of the prescriptions written for the same combination of medications?

**Relevance:**



- This is a prescribing behavior that has been observed in documented “pill mill” cases. It is very questionable that in the usual course of practice, most or all individuals would require the exact same combination of controlled substances and doses as part of a legitimate medical regimen.

**4 *Prescriber provides the same diagnosis for the majority of individuals***

**Key Considerations**

- Does the prescriber practice in a very narrow, specialize area of medicine?
- Is it plausible that all individuals have the same diagnosis? Does it appear unrealistic?

**Relevance:**

- The lack of individualized treatment for these individuals could be indicative of improper prescribing practices and an indication that the prescriptions were not written for a legitimate medical purpose.

**5 *Prescriber commonly writes narcotic prescriptions for individuals between 18 to 35 years old, especially chronic therapy***

**Key Considerations**

- Does the prescriber specialize in a particular field that is more applicable to this age group, for example Sports Medicine?
- Are individuals in this age range receiving short or long-term narcotic therapy?
- Is the prescriber located in an area with a younger population (e.g., near a college campus)?

**Relevance:**

- While drug abuse can occur at any age, there tends to be a higher prevalence of abuse within this age range.
- Outside of the oncology or hospice setting, there is generally a low incidence rate of individuals in this age range requiring long-term opiate therapy. Diagnosis and treatment plan are key pieces of information to obtain when evaluating appropriateness.

**6 *Knowledge that prescriber operates on a “cash only” basis – does not accept insurance.***

**Relevance:**

- There have been documented cases of “pill mills” operating on a cash-only basis. While operating on a cash-only basis does not necessarily imply that the prescriber is running a “pill mill” it is a red flag that should be considered in light all any other red flags that may be present when evaluating a prescription.

## **II. Individual Red Flags**

### **1 Individual pays cash, or insists on paying cash for controlled substances even though insurance is on file**

#### ***Key Considerations:***

- Does the individual have a prescription plan on file? If they do, why do they not want to use the coverage?
- If prescription coverage exists, is the individual attempting to use the coverage only for non-controls drugs, while wanting to pay cash for controlled substances?

#### ***Relevance:***

- It is a well-established trend that individuals seeking to illegitimately obtain controlled substances will often attempt to pay cash for the prescriptions. This may be due in part to their belief that their behavior will go undetected if submitting claims to the prescription plan is circumvented.

### **2 Evidence of “doctor shopping” exists**

#### ***Key Considerations:***

- When reviewing the individual profile and/or state PMP site (where available), has the individual received prescriptions for controlled substances in the same therapeutic class from more than one prescriber? If yes, are the prescribers associated as part of the same group practice, or from different practices?
- Is the individual receiving controlled substances from multiple prescribers during the same (i.e. overlapping) period of time?

#### ***Relevance:***

- Prescription drug abusers will often attempt to obtain controlled substances from multiple prescribers during adjacent or overlapping periods of time. The prescribers being visited are typically not part of the same group practice, and many times may be located in different communities.
- It is not uncommon in large group practices for individuals to see different prescribers in the group practice at different points in time. Therefore, particular attention should be paid to the time periods in which the prescriptions have been filled, specifically to determine if any overlapping time periods exist.

**3 Evidence of “pharmacy shopping” exists**

***Key Considerations:***

- When reviewing the state PMP site (where applicable) has the individual received prescriptions for controlled substances in the same therapeutic class from more than one pharmacy?
- Is the individual receiving controlled substances from multiple pharmacies during the same (i.e. overlapping) period of time?
- Does the individual’s profile only contain controlled substance prescriptions?
- Does the individual ask only for the controlled substance prescriptions to be filled? The individual does not want the non-controlled substances prescribed on the same prescription blank to be filled.

***Relevance:***

- Prescription drug abusers will often attempt to obtain controlled substances from multiple pharmacies during adjacent or overlapping periods of time. The pharmacies may be located in different communities and can be considerable distances apart.
- An individual may fill their prescriptions near their home, work or prescriber. It’s important to identify pharmacies that an individual fills prescriptions at that are not located near home, work or prescriber and cannot be reasonably explained.

**4 Individual resides outside of the trade area of your pharmacy**

***Key Considerations:***

- Why is the individual traveling to go to your pharmacy?
- Does the individual pass other pharmacies on the way to your pharmacy?

***Relevance:***

- In an attempt to avoid detection, prescription drug abusers will often attempt to fill controlled substances from pharmacies outside of their geographical area.
- There are documented cases where drug abusers will travel great distances - often across many states - to obtain controlled substances for illicit use.
- Prescription drug abusers will often attempt to obtain controlled substances prescriptions from prescribers outside of their geographical area.

**5 Individual is on short acting pain medication(s) for extended period of time without the addition of a long acting drug**

***Key Considerations:***

- Has the individual been receiving only short acting medications for treatment of long term pain without the addition of an extended release drug?
- Can the prescriber provide any explanation why an extended release medication is not prescribed and what other treatment plan is included in the individual's overall pain treatment plan?

**Relevance:**

- Abuse is most common and typically identified with short acting drugs, especially narcotic analgesics.
- If a prescriber or agent is not able to provide clinical reasoning or is unwilling to discuss the individual's condition with the pharmacist, this behavior may be indicative of illegitimate use.

**6 The individual's statements and conduct or behavior suggest abuse of controlled substances**

**Key Considerations:**

- Does the individual use street names when discussing controlled substances (i.e. "~~Mallineroed~~ Mallinckrodt blues", "M's", "Percs", "Reds", "Oxy", "OC", etc.)?
- Is the individual presenting to the pharmacy in an "intoxicated" or "incoherent" state?
- Is behavior exaggerated (over friendly and talkative) or very nervous and anxious.

**Relevance:**

- Inappropriate individual conduct and knowledge of street names are important indicators of abuse.
- Prescription drug abusers may be reluctant to provide personal information needed to assist the pharmacist in the prescription review and consultation process.
- Abuse is commonly identified when a individual consistently needs an early refill because they lost their medication or are leaving town a few days before the prescription is due to be filled.

**7 Individual routinely attempts to obtain an early refill on controlled substances**

**Key Considerations:**

- Is the individual taking the medication properly? Have dosing instructions been changed by prescriber?
- Are DUR edits flagging the prescription as too early to refill?
- Does the individual frequently offer explanations to justify the early refill (i.e. "somebody stole my medication" or "I lost my medication"?)

**Relevance:**

- Frequent early fills can be an indication of either intentional abuse or unintentional misuse.



- Individual history should be reviewed to identify if an early refill pattern exists. A pattern of early fills can indicate abuse.

**8 Individuals have suspect relationships with each other**

**Key Considerations:**

- Does one individual drop off and pick up prescriptions for multiple other individuals?
- Does a group of individuals come into the pharmacy with the same prescriptions from the same prescriber?
- Do all the individuals live together and/or are they all related?

**Relevance:**

- Prescription drug abusers may attempt to use one individual or may travel in groups to obtain controlled substances from pharmacies.
- Prescription drug abusers may use one common address in the attempt to obtain controlled substances from pharmacies.

**III. Prescription Red Flags**

**1 Prescriptions presented represent a “cocktail” of commonly abused drugs**

**Key Considerations:**

- Are prescriptions for any combination of the following controlled substances presented: narcotic analgesics, benzodiazepines, muscle relaxants (ex. Carisoprodol (Soma)), or stimulants? Does a review of the individual profile or state PMP reveal this combination of agents?
- Does the prescriber routinely prescribe this same combination of drugs, in similar strengths, for most individuals?

**Relevance:**

- The abuse of any combination of the above controlled substances is a trend that has been well established by law enforcement officials.
- The combination of a narcotic, a benzodiazepine, and a muscle relaxant would have a synergistic effect on a individual’s central nervous system and cause respiratory depression thus posing a substantial risk to any individual actually taking the drugs as prescribed.
- It has been observed by law enforcement that many prescribers writing for illegitimate purposes will often write prescriptions for the same combination of drugs, usually in the same strength, for all individuals.

**2 Prescription presented is for an unusually large quantity or high starting dose**

**Key Considerations:**

- Is the quantity and strength of the medication prescribed appropriate for the indication?
- Is the daily dose prescribed higher than the normal daily dose?
- Is the prescriber writing prescription(s) without any consideration of the individual (age, weight, etc.)?

**Relevance:**

- A large quantity of a medication or an unusually high starting dose for an acute ailment may be an indication that the prescription was not written for a legitimate medical purpose.
- It has been observed that many prescribers writing for an illegitimate medical purpose will write prescriptions for the same dose and duration of therapy no matter the age or weight of the individual.

**3 Individual insists on the brand name drug, or a certain generic company's drug being dispensed.****Key Considerations:**

- What is the individual's rationale for insisting on a particular brand name or generic manufacturer?

**Relevance:**

- Brand name and certain generic company drugs typically command a higher street value than do other drugs due to the fact that they are easily identified by their trade dress and are more readily recognizable in and amongst drug abusers involved in illicit drug trafficking.
- Referring to prescription products by their street names is highly indicative of abuse and illegitimate use.

**4 Prescriptions appear to be altered or duplicated****Key Considerations**

- Does any information in particular the quantity, strength, or refills appear altered on the prescription?
- Is the prescription written in different colors of ink/pencil?
- Does the handwriting differ throughout the prescription?
- Does the prescription look like it has been duplicated by a scanner or copier with a signature added in ink?

**Relevance:**

- Prescription drug abusers will attempt to alter prescriptions in order to obtain larger quantities and or refills.

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- Any prescription can be altered, but prescriptions from emergency rooms, immediate care centers, and hospitals are typically targeted by drug abusers.

4. ~~Prescriptions written by hospital emergency departments~~

~~Key considerations:~~

- ~~Has the quantity being altered? (This was mentioned in the DEA Pharmacist manual)~~

~~Relevance:~~

- ~~People try to alter the quantity and present the prescription to the Pharmacy~~